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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/026,188

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

10/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/026,188

Applicant(s)

ZUKER ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 4-9 12 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1) Claims 1, 4 to 9, 12 and 14 to 19 are pending in the instant application. Claims 1, 12 and 17 have been amended and claims 18 and 19 have been added as requested by Applicant in the correspondence filed 12 July of 2007.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4) Claims 1, 4 to 9, 12 and 14 to 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "wherein the functional effect is a change other than a change in Ca^{++} influx through a TC-ICS; thereby identifying the compound that modulates taste signaling in taste cells" is new matter that is wholly unsupported by the instant specification as filed. Nowhere in the instant application, as filed, is there a disclosure as to whether TC-ICS mediated Ca^{++} influx is supposed to occur through the TC-ICS protein described therein or not.

The text in the fourth paragraph on page 10 of the instant specification quite ambiguously states that "[t]he phrase 'functional effect' in the context of assays for testing compounds that modulate TC-ICS-mediated taste transduction includes the

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determination of any parameter that is indirectly or directly under the influence of TC-ICS", including "changes in ion flux, membrane potential, current flow, transcription, G-protein binding, GPCR phosphorylation or dephosphorylation, signal transduction, receptor-ligand interactions, second messenger concentrations (e.g., cAMP, IP3, or intracellular Ca^{2+}), *in vitro*, *in vivo*, and *ex vivo* and also includes other physiologic effects such increases or decreases of neurotransmitter or hormone release". There is no disclosure in the specification as to whether a measured change in intracellular Ca^{++} is supposed to be "directly" or "indirectly" "influenced" by the modulation of a protein of the instant invention. At best, the text on page 24 of the instant specification teaches that "a change in the level of second messengers, such as IP3, DAG, or Ca^{2+} can be used to assess TC-ICS function" without making a distinction between changes that occur by the direct action of a test compound upon a TC-ICS protein and changes that result from an indirect effect. The instant specification does not identify a specific mechanism through which the modulation of TC-ICS is supposed to effect intracellular Ca^{++} in response to a test compound.

5) Claims 1, 4 to 9, 12 and 14 to 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for those reasons of record as applied to claims 1, 4 to 9, 12 and 14 to 17 on page 5 of the office action mailed 08 January of 2007. The instant specification describes a protein identified therein as a taste receptor cell specific ion channel subunit (TC-ICS). No functionality has been demonstrated for this protein. It is presumed to be a functional protein because it is a naturally occurring human protein and humans do not generally produce

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inoperable proteins. TC-TCS is presumed to be involved in taste perception only because it appears to be expressed exclusively in taste cells (circumvallate papillae). Whereas the text on page 54 of instant specification, for example, alleges that "modulation of taste transduction" can be "assayed by measuring changes in intracellular Ca^{2+} levels, which change in response to modulation of the TC- ICS signal transduction pathway via administration of a molecule that associates with TC- ICS", there is no evidence or sound scientific reasoning provided by the instant specification that TC-ICS is capable of functioning as a homomeric unit or of "modulating" intracellular Ca^{2+} levels.

Further, the instant specification does not disclose, with specificity, precisely what effect the activation or inhibition of TC-ICS activity can be expected to have upon an individual. Absent this information, one of ordinary skill in the art of molecular biology can not practice the claimed assay and employ the information obtained therefrom in a specific and substantial utility in currently available form (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),

The following is an excerpt from M.P.E.P. 2138.05:

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167

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USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.)."

The claimed assay does not have specific use in currently available form because one can not predict with reasonable certainty that a TC-ICS protein of the instant invention is capable of functioning as a homomeric protein, that this homomeric protein actually influences intracellular Ca^{2+} levels, whether a compound that stimulates the activity of TC-ICS enhances or inhibits a sensation of taste, and whether that taste sensation is sweet, bitter and/or umami. Clearly, the instant specification fails to disclose how to use the claimed assay without the need for substantial further inventive contributions.

Applicant has essentially traversed this rejection on the premise that the measurement of changes in intracellular Ca^{2+} levels is a routine practice in the art. It certainly is. However, the rejection is maintained because the instant specification leaves it to the artisan to make the substantial inventive contribution of determining if TC-ICS is capable of effecting intracellular Ca^{2+} levels at all, if the stimulation of TC-ICS elevates or suppresses intracellular Ca^{2+} levels, and of establishing a nexus between the activation of TC-ICS and the preceptor of a specific taste.

6) Claims 1, 4 to 9, 12 and 14 to 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention essentially for those reasons of record as applied to claims 1, 4 to 9, 12 and 14 to 17 in the second paragraph on page 4 of the office action mailed 08 January of 2007. as stated therein, the phrase "or a

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change in intracellular Ca^{2+} is indefinite, alone, because it does not set forth what is actually changing with regard to "intracellular Ca^{2+} ", e.g. concentration, localization, isotopic composition? Thus the phrase appears to be incomplete and the artisan could not be sure if he or she were actually practicing the claimed invention. This is also true for the limitations "a change in intracellular cAMP, cGMP, IP3 or DAG". Applicant urges that "any change in intracellular Ca^{++} concentration can be routinely measured". This is not the issue. The claim limitation at issue does not require one to measure a change in the **concentration** of anything, only a "change" in intracellular cAMP, cGMP, IP3, DAG or Ca^{2+} .

Interference

7) The Margolskee et al. patent publication (US 20020037515) has been removed as a reference against the instant claims under 35 U.S.C. § 102(e) by the Zuker et al. declaration filed 02 May of 2005. Whether the instant claims potentially interfere with the Margolskee et al. patent application will not be considered until the instant claims are otherwise in condition for allowance.

Conclusion

8) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JOHN D. ULM
PATENT EXAMINER
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